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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/673,222	12/04/2000	Ronald D. Vale	UCSD-04765	3800

7590

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EXAMINER

HARRIS, ALANA M

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 12/03/2003

*24*

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/673,222

Applicant(s)

VALE ET AL.

Examiner

Alana M. Harris, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-25, 43-46 and 48-124 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-25, 52, 53 and 86-124 is/are allowed.
- 6) ☒ Claim(s) 43-46, 48-51 and 54-59 is/are rejected.
- 7) ☒ Claim(s) 60-85 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 19.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

**DETAILED ACTION**

***Response to Amendments and Arguments***

1. Claims 1-25 and 43-46 and 48-124 are pending.

Claims 1, 2, 9-11, 16, 17, 21, 25, 43, 44, 48, 52, 53, 55, 58 and 59 have been amended.

Claims 60-124 have been added.

Claims 26-42 have been cancelled.

Claims 1-25, 43-46 and 48-124 are examined on the merits.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Information Disclosure Statement***

3. Applicants filed a supplemental information disclosure statement on April 7, 2003, which contained all the pertinent information. The Examiner has considered these references.

***Withdrawn Objections***

***Specification***

4. The disclosure is no longer objected to because all the informalities listed in Paper number 16, page 3, paragraph 5 have been corrected.

***Claim Objections***

5. Claims 17, 21, 25, 55, 58 and 59 are no longer objected to because all of the informalities listed in the Paper number 16, pages 3 and 4, paragraph 6 have been corrected.

***Withdrawn Rejections***

***Claim Rejections - 35 USC § 112***

6. The rejection of claims 2, 4, 9-12 and 55-59 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn.

***Claim Rejections - 35 USC § 102***

7. The rejection of claims 43-46 and 49-54 under 35 U.S.C. 102(b) as being anticipated by McNally and Vale (Cell 75:419-425, November 5, 1993/ Reference #92 of IDS) is withdrawn.

***Double Patenting***

8. The provisional rejection of claims 43-51 and 55-59 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 43-71 of copending Application No. 09/724,595 (filed November 28, 2000) is withdrawn in light of the expressed abandonment of the '595 application.

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9. The provisional rejection of claims 43-51 and 55-59 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 51 and 55-66 of copending Application No. 09/724,602 (filed November 28, 2000) is withdrawn in light of the expressed abandonment of the '602 application.

10. The rejection of claims 11-16 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 11-16 of copending Application No. 09/724,887 (filed November 28, 2000) is withdrawn in light of the expressed abandonment of the '887 application.

11. The provisional rejection of claims 43-59 under 35 U.S.C. 101 as claiming the same invention as that of claims 43-59 of copending Application No. 09/724,596 (filed November 28, 2000) is withdrawn in light of the expressed abandonment of the '596 application.

12. The provisional rejection of claims 1-10 under 35 U.S.C. 101 as claiming the same invention as that of claims 1-10 of copending Application No. 09/724,887 (filed November 28, 2002) is withdrawn in light of the expressed abandonment of the '887 application.

***New and Maintained Grounds of Objection and Rejection***

***Claim Objections***

13. Claims 60-72 are objected to under 37 CFR 1.75 as being a substantial duplicate of claims 73-85. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

14. Claim 17 is objected to because of the following informality: it contains a period in the midst of text on line 3. It is not clear if more text should be included in the claim or that this is a typographical error. Correction is required.

***Specification***

15. The amendment filed April 7, 2003 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material, which is not supported by the original disclosure, is as follows: the drawings, which include changes in the amino acid sequence of Figure 1 and Figure 1B. There is no support for the change from G to H at position 89 in Figure 1A or changing the last three Gs in Figure 1B of the original specification as filed or in the priority documents, PCT/US99/08086 and provisional application 60/081,734.

Applicant is required to cancel the new matter in the reply to this Office Action.

***Claim Rejections - 35 USC § 103***

16. The rejection of claims 43-46 and 48-51 under 35 U.S.C. 103(a) as being unpatentable over McNally and Vale (Cell 75:419-425, November 5, 1993/ Reference #92 of IDS), in view of Bonne et al. (The Journal of Biological Chemistry 260(5): 2819-2825, March 10, 1985) is maintained.

Applicants argue that a *prima facie* case of obviousness has not been established, as well as the references fail to disclose all the claims' limitations, there is no motivation to combine the elements and a reasonable expectation of success has not been established. Applicants also note that Bonne teaches away for the claimed invention and in some circumstances DAPI is not a good probe. These points of view have been carefully considered, but found unpersuasive.

The Examiner did set forth that McNally and Vale did not teach that the microtubule is labeled with DAPI, however the teaching of Bonne meets the deficiency of the former reference and in essence establishing a clear *prima facie* case of obviousness. McNally and Vale do teach an assay to characterize a test agent, katanin. Applicants' claim contains a Markush group consisting of seven different labels. Bonne teaches one of the seven and clearly notes that "DAPI ...permitted [one] follow the kinetics of polymerization... and direct visualization of microtubules...", see page 2824, column 2, paragraph 2. Applicants have not provided scientific evidence that precludes DAPI from not being effectual in the claimed invention. Simply noting that DAPI did not work in one circumstance is not sufficient in precluding that it would not work in another circumstance. And furthermore the citing of Bonne, page 2824, column 2, third

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paragraph noting that DAPI is not a good probe to visualize microtubules in cells is in the context of an *in vivo* study and not an *in vitro* study as dictated by the current set of examined claims. The reasoning set forth above and in Paper number 16 meets the requirements for presenting a *prima facie* case. Accordingly, the rejection is maintained.

17. Claims 43-46, 48-51 and 55-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over McNally and Vale (Cell 75:419-425, November 5, 1993/ Reference #92 of IDS), in view of Bonne et al. (The Journal of Biological Chemistry 260(5): 2819-2825, March 10, 1985) and U.S. Patent number 6,083,763 (filed December 31, 1997).

The teachings of McNally and Vale and Bonne have been presented in the 103(a) rejection. McNally and Vale, nor Bonne do not teach that the disclosed method is performed in an array, which comprises a microtitre plate and a multiplicity of at least 48 reaction mixtures wherein each reaction mixture comprises a distinct and distinguishable domain of said array with a plurality of agents.

However, U.S. Patent #6,083,763 does teach that a multiplexed molecular analysis system is useful for analyzing and quantifying several molecular targets within a sample substance using an array having a plurality of biosites upon which the sample substance is applied, see column 4, lines 30-38. The said system may comprise a microplate based array which can be used for screening analysis, wherein a microplate configured with a four by four (4x4) matrix of biosites in each of the 96 wells would be able to perform a total of 1536 nearly simultaneous tests, see column 4, lines 40-45.



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The system allows for detecting or the detection of fluorescent labeling, as well as the processing of images to determine information about target molecules within a given sample that leads to analysis output and fast data acquisition, see column 10, lines 17-22; column 27, lines 26-48.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to utilize a multiplexed molecular analysis method comprising a microtitre based array in a method of screening. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by the teachings of the patent because a multiplexed molecular analysis system can be advantageous due to the commercially availability of reaction vessels such as a microtitre plate which contains at least one reaction chamber, but can contain 8, 24, 96 or 384 reaction chambers. This allows performing in parallel a large set of assays yielding high throughput, low cost, ease in which fluorescent labeling can be modified to achieve the highest signal-to-noise ratio and detection, as well as automated operation, see columns 5 and 6; column 25, lines 26-37.

18. Claims 43-46, 48-51 and 55-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over McNally and Vale (Cell 75:419-425, November 5, 1993/ Reference #92 of IDS), in view of Bonne et al. (The Journal of Biological Chemistry 260(5): 2819-2825, March 10, 1985).

The teachings of McNally and Vale and Bonne have been presented in the 103(a) rejection. McNally and Vale, nor does Bonne teach that the disclosed method

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further comprises listing the agents that alter microtubule polymerization, depolymerization, or severing into a database of therapeutic lead compounds that act on the cytoskeletal system.

However, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to comprise a list of molecules that alter the polymerization, depolymerization and severing of microtubules and enter that list of agents into a database or some other form of communication. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success because it would be convenient to provide a listing of agents that alter microtubule polymerization, depolymerization, or severing into database of compounds that act on the cytoskeletal system. The compilation of such compounds would aid a practitioner studying eukaryotic cells to assess molecules involved in the determination of cell architecture, intracellular transport, modulation of surface receptors, mitosis, cell motility and differentiation.

### ***Conclusion***

19. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (703) 306-5880. The examiner can normally be reached on 7:00 am to 4:30 pm, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached on (703) 308-3995. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4315.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Alana M. Harris, Ph.D.  
1 December 2003